IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ELAN CORPORATION, PLC and ELAN PHARMA INTERNATIONAL LTD., Plaintiffs, v. BARR LABORATORIES, INC., Defendant.	Honorable Sue L. Robinson Civil Action No.: 1:07-cv-00736-SLR **DEFENDANT BARR LABORATORIES, INC.'S ANSWER, AFFIRMATIVE DEFENSES AND COUNTERCLAIMS**

DEFENDANT BARR LABORATORIES, INC.'S
ANSWER, AFFIRMATIVE DEFENSES AND COUNTERCLAIMS

Defendant Barr Laboratories, Inc. ("Barr"), by and through its undersigned attorneys, answers the Complaint of Plaintiffs Elan Corporation, PLC and Elan Pharma International LTD. (collectively, "Elan" or "Plaintiffs") as follows:

ANSWER

Parties

1. On information and belief, Barr admits the allegation in Paragraph 1 of the Complaint.

2. On information and belief, Barr admits the allegation in Paragraph 2 of the Complaint.

3. Barr admits that it is a Delaware corporation having a place of business at 2 Quaker Road, Pomona, New York 10970, and engages in the manufacture and sale of drug products. Barr denies any and all other allegations set forth on Paragraph 3 of the Complaint.

Nature of the Action

4. Paragraph 4 is a characterization of Plaintiffs' Complaint and contains legal conclusions rather than allegations of fact to which no response is required. To the extent that a response is required, Barr admits that Plaintiffs' Complaint purports to assert an action for patent infringement of United States Patent Nos. 6,228,398 ("'398 patent") and 6,730,325 ("'325 patent"). Barr also admits that Plaintiffs seek relief under the patent laws of the United States, 35 United States Code, but specifically denies that Plaintiffs are entitled to such relief. To the extent that Paragraph 4 of the Complaint contains any additional allegations, Barr denies them.

5. Paragraph 5 contains legal conclusions to which no response is required. To the extent that a response is required, Barr admits that this Court has subject matter jurisdiction over Plaintiffs' claims.

6. Paragraph 6 contains legal conclusions to which no response is required. To the extent that an answer is required, Barr admits that this Court has personal jurisdiction over Barr.

7. Paragraph 7 states a legal conclusion to which no response is required. To the extent that a response is required, Barr admits that venue for this action is proper in this Court.

FACTUAL BACKGROUND

8. Barr admits that the patent on its face lists Elan as the assignee of the '398 patent, entitled "Multiparticulate Modified Release Composition." Barr further admits that the patent on its face states that the '398 patent was issued on May 8, 2001, but specifically denies that the patent was duly or legally issued. Barr admits that a copy of the '398 patent was

attached to the Complaint as Exhibit A. To the extent that Paragraph 8 of the Complaint contains any additional allegations, Barr denies them.

9. Barr admits that the patent on its face lists Elan as the assignee of the '325 patent, entitled "Multiparticulate Modified Release Composition." Barr further admits that the patent on its face states that the '325 patent was issued on May 4, 2004, but specifically denies that the patent was duly or legally issued. Barr admits that a copy of the '325 patent was attached to the Complaint as Exhibit B. To the extent that Paragraph 9 of the Complaint contains any additional allegations, Barr denies them.

10. Barr admits that the United States Food and Drug Administration ("FDA") website lists that New Drug Application ("NDA") No. 21-802 was approved on May 26, 2005 for capsules containing dexmethylphenidate hydrochloride which are indicated for the treatment for Attention Deficit Hyperactivity Disorder under 21 U.S.C. § 355(a). Barr further admits that the '398 patent and the '325 patent are listed in the Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") for FOCALIN® XR capsules. To the extent that Paragraph 10 of the Complaint contains any additional allegations, Barr denies them.

11. Barr admits that it has submitted to the FDA ANDA No. 79-091 pursuant to 21 U.S.C. § 355(j), to obtain FDA approval for the commercial manufacture, use, offer to sell, sale, or importation into the United States of dexmethylphenidate hydrochloride extended release capsules in 5 mg, 10 mg, 15 mg, and 20 mg dosage forms (collectively, "Barr's Proposed Products"). To the extent that Paragraph 11 of the Complaint contains any additional allegations, Barr denies them.

12. Barr admits that it sent the Barr Letter to Plaintiffs on October 5, 2007 to give notice that Barr had filed ANDA No. 79-091, for the purpose of obtaining approval to

engage in the commercial manufacture, use, offer to sell, sale and/or importation of methylphenidate hydrochloride extended release capsules into the United States prior to the expiration of the '398 and '325 patents. To the extent that Paragraph 12 of the Complaint contains any additional allegations, Barr denies them.

13. Admitted.

COUNT I

14. Barr hereby incorporates by reference its answers from Paragraphs 1 to 13 as if fully set forth herein.

15. Barr admits that it has submitted ANDA No. 79-091 to obtain FDA approval for the commercial manufacture, use, offer to sell, sale, or importation of Barr's Proposed Products into the United States before the expiration of the '398 patent, which can constitute a technical act of infringement under 35 U.S.C. § 271(e)(2). Barr specifically denies that ANDA No. 79-091 infringes the '398 patent and the remaining allegations of Paragraph 15 of the Complaint.

16. Denied.

17. Barr admits that when it filed its ANDA seeking approval to manufacture and sell methylphenidate hydrochloride extended release capsules, it was aware of the existence of the '398 patent. Barr denies each and every remaining allegation in Paragraph 17 of the Complaint and specifically denies that this is an exceptional case.

COUNT II

18. Barr hereby incorporates by reference its answers from Paragraphs 1 to 13 as if fully set forth herein.

19. Barr admits that it has submitted ANDA No. 79-091 to obtain FDA approval for the commercial manufacture, use, offer to sell, sale, or importation of Barr's

Proposed Products into the United States before the expiration of the '325 patent, which can constitute a technical act of infringement under 35 U.S.C. § 271(e)(2). Barr specifically denies that ANDA No. 79-091 infringes the '325 patent and the remaining allegations of Paragraph 19 of the Complaint.

20. Denied.

21. Barr admits that when it filed its ANDA seeking approval to manufacture and sell methylphenidate hydrochloride extended release capsules, it was aware of the existence of the '325 patent. Barr denies each and every remaining allegation in Paragraph 21 of the Complaint and specifically denies that this is an exceptional case.

Prayer For Relief

Barr denies that Plaintiffs are entitled to any relief from the Court.

AFFIRMATIVE DEFENSES

Barr sets forth the following affirmative and other defenses. Barr does not intend hereby to assume the burden of proof with respect to those matters as to which, pursuant to law, Plaintiffs bear the burden.

First Affirmative Defense

(Invalidity of '398 Patent)

1. One or more claims of United States Patent No. 6,228,398 are invalid for failure to satisfy the provisions of one or more of sections 101, 102, 103, and/or 112 of Title 35 of the United States Code.

Second Affirmative Defense

(Invalidity of '325 Patent)

2. One or more claims of United States Patent No. 6,730,325 are invalid for failure to satisfy the provisions of one or more of sections 101, 102, 103, and/or 112 of Title 35 of the United States Code.

Third Affirmative Defense

(Noninfringement of '398 Patent)

3. The manufacture, use, sale, or offer for sale of Barr's dexmethylphenidate hydrochloride extended release ANDA product has not infringed, does not infringe, and would not, if marketed, infringe (directly, indirectly, contributorily, by inducement or otherwise) any valid and enforceable claims of the '398 patent.

Fourth Affirmative Defense

(Noninfringement of '325 Patent)

4. The manufacture, use, sale, or offer for sale of Barr's dexmethylphenidate hydrochloride extended release ANDA product has not infringed, does not infringe, and would

not, if marketed, infringe (directly, indirectly, contributorily, by inducement or otherwise) any valid and enforceable claims of the '325 patent.

Fifth Affirmative Defense

(Failure to State a Claim)

5. Plaintiffs' Complaint, in whole or in part, fails to state a claim upon which relief can be granted.

Sixth Affirmative Defense

6. Any additional defenses that discovery may reveal.

COUNTERCLAIMS

Barr Laboratories, Inc. ("Barr") brings the following counterclaims against Plaintiffs Elan Corporation, PLC and Elan Pharma International LTD. (collectively, "Elan"), for a declaratory judgment that U.S. Patent Nos. 6,228,398 ("'398 patent") and 6,730,325 ("'325 patent") are invalid and not infringed by Barr's ANDA Product.

Defendant/Counterclaim Plaintiff Barr, by and through its undersigned attorneys, hereby alleges, for its counterclaims against Plaintiffs/Counterclaim Defendant Elan as follows:

Parties

1. Counterclaim-Plaintiff Barr is a corporation organized and existing under the laws of Delaware, having its corporate offices and principal place of business at Two Quaker Road, P.O. Box 2900, Pomona, New York 10970.

2. On information and belief, Counterclaim-Defendant Elan Corporation, PLC is an Irish corporation having its principal place of business at Treasury Building, Lower Grand Canal St., Dublin 2, Ireland.

3. On information and belief, Counterclaim-Defendant Elan Pharma International LTD. is an Irish corporation having its principal place of business at Monksland, Athlone County, Westmeath, Ireland.

4. Elan Pharma International LTD. is a subsidiary of Elan Corporation, PLC.

5. Counterclaim-Defendants Elan Corporation and Elan Pharma International LTD. are collectively referred to herein as "Counterclaim-Defendants."

Jurisdiction and Venue

6. This action arises under the patent laws of the United States of America and the Declaratory Judgment Act. This Court has subject matter jurisdiction pursuant to Title

28, United States Code Sections 1331, 1338(a), 2201, 2002 and Title 21, United States Code Section 355(j)(5)(C).

7. This Court has personal jurisdiction over Counterclaim-Defendants on the basis of, *inter alia*, their contacts with Delaware relating to the subject matter of this action, including having filed this suit, their continuous and systematic contacts in Delaware, and their derivation of substantial revenue from services or things produced or consumed in Delaware.

8. Venue is proper in this Court pursuant to Title 28, United States Code 1391(b) &(c) and 1400(b).

Background

FDA Approval Of New Brand Name Drugs.

9. The Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C. § 301 et seq., as amended by the Hatch-Waxman Amendments, sets forth the rules that the Food and Drug Administration ("FDA") follows when considering whether to approve the marketing of both brand-name and generic drugs.

10. Under the FFDCA, an applicant seeking to market a new brand-name drug must prepare a New Drug Application ("NDA") for consideration by FDA. *See* 21 U.S.C. § 355.

11. An NDA must include, among other things, the number of any patent that claims the "drug" or a "method of using [the] drug" for which the NDA was submitted and for which a claim of patent infringement could reasonably be asserted against an unauthorized party. *See* 21 U.S.C. § 355(b)(1) – (c)(2); 21 C.F.R. § 314.53(b)(1) – (c)(2).

12. Upon approval of the NDA, FDA publishes patent information for the approved drug in "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly known as the "Orange Book." 21 C.F.R. § 314.53(e).

13. FDA's duties with respect to Orange Book listings are purely ministerial. If the NDA-holder submits a patent to FDA for listing in the Orange Book, the patent is listed in the Orange Book. *See* 21 U.S.C. § 355(b)(1); 21 C.F.R. § 314.53(e) – (f). FDA does not substantively review the submitted patent information to ensure that it is accurate or that the NDA holder properly submitted it in connection with the NDA drug (or "reference listed drug"), but instead relies on the NDA holder to properly list the patents.

FDA Approval Of New Generic Drugs.

14. Generic drugs are versions of brand-name prescription drugs that typically contain the same active ingredients, but not necessarily the same inactive ingredients, as the brand-name original.

15. In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act, also known as the Hatch-Waxman Amendments, to the FFDCA. *See* Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified at 21 U.S.C. § 355 and 35 U.S.C. §§ 156, 271(e)). Congress passed Hatch-Waxman, which simplified the procedure for obtaining approval of generic drugs, for the purpose of decreasing the cost of pharmaceuticals through increased competition.

16. Under the Hatch-Waxman Amendments, a generic manufacturer submits to FDA what is called an Abbreviated New Drug Application ("ANDA").

17. To receive FDA approval of its ANDA, an applicant must show, inter alia, that its generic drug is "bioequivalent" to the reference listed drug, and that it contains the same active ingredient, conditions of use, route of administration, dosage form, strength, and labeling as the reference listed drug. *See* 21 U.S.C. § 355(j)(2)(A); 21 C.F.R. § 314.94(a).

18. If the applicant meets these requirements, it is entitled to rely on the NDA holder's clinical studies performed on the reference listed drug to show the product's safety and efficacy.

19. An ANDA must also contain a "certification" to each patent that the NDA holder has submitted to FDA for listing in the Orange Book in connection with the reference listed drug. *See* 21 U.S.C. § 355(j)(2)(A)(vii); 21 C.F.R. § 314.94(a)(12).

20. A "paragraph IV" certification asserts that the listed patent is invalid, unenforceable, and/or will not be infringed and, on that basis, the applicant seeks FDA approval of the generic product prior to patent expiration. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV); *see also* 21 C.F.R. § 314.94(a)(12)(i)(A)(4).

21. An applicant submitting an ANDA containing a paragraph IV certification must notify both the patent holder and NDA holder of each of its paragraph IV certifications. *See* 21 U.S.C. § 355(j)(2)(B).

22. Upon receiving notice of the paragraph IV certifications, the patent holder has 45 days in which to file an infringement suit against the generic manufacturer. *See* 21 U.S.C. § 355(j)(5)(B)(iii); 35 U.S.C. § 271(e)(2)(A).

23. Patent holders have a significant strategic incentive to list patents in the Orange Book and file suit within 45 days of receiving notice of a paragraph IV certification because doing so, regardless of merit, prevents FDA from approving the generic maker's ANDA for a period of 30 months, absent certain exceptions requiring court action. *See* 21 U.S.C. § 355(j)(5)(B)(iii). Among other things, if the court hearing the infringement action decides the patent is valid, enforceable, and would be infringed by the product proposed in the ANDA, FDA will not approve the ANDA until the patent expires. *Id.* If, however, the court hearing the

infringement action rules before the expiration of the 30-month period that the patent is invalid, unenforceable, or not infringed, FDA may approve the ANDA effective on the date when the court enters the judgment. *Id.*

Acts Giving Rise To Barr's Counterclaims

24. Upon information and belief, Elan is, and has been since the time of the issuance of the '398 patent and the '325 patent, the assignee and owner of the patents.

25. Barr filed with the FDA an ANDA, which the agency assigned No. 79-091, with a Paragraph IV Certification to obtain approval to engage in the manufacture, use or sale of 5 mg, 10 mg, 15 mg, and 20 mg, of hydrochloride salt of *d-threo*-methylphenidate extended release capsules.

26. In its ANDA, Barr certified pursuant to 21 U.S.C. § 505(j)(2)(A)(vii)(IV) ("Paragraph IV") of the act that, in Barr's opinion and to the best of its knowledge the claims of the '398 and the '325 patents are invalid and/or not infringed by the manufacture, use or sale of Barr's ANDA products.

27. On October 5, 2007, Barr sent to Plaintiffs a statutorily-required notice letter containing a detailed factual and legal statement as to why the '398 and '325 patents were invalid, unenforceable and/or not infringed by Barr's ANDA products. Within its notice letter and pursuant to 21 U.S.C. § 355(j)(5)(C), Barr offered to provide its ANDA to Plaintiffs.

28. On November 16, 2007, Plaintiffs filed their patent infringement lawsuit against Barr. Barr was served with Plaintiffs' Complaint on November 19, 2007. In its complaint, Plaintiffs allege that Barr's ANDA products will infringe the '398 and '325 patents, which Barr has denied herein.

29. This case is an exceptional one, and Barr is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

First Counterclaim

Declaration of Invalidity of the '398 Patent

30. Barr hereby repeats and reiterates the allegations of Paragraphs 1 through 29 as if fully set forth herein.

31. This counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and seeks a declaration that claims of the '398 patent is invalid.

32. Plaintiff/Counterclaim Defendant Elan alleges that the '398 patent is infringed, valid, and enforceable, and Barr denies those allegations.

33. A present, genuine, and justiciable controversy exists between Barr and Plaintiff/Counterclaim Defendant Elan regarding the validity of the '398 patent.

34. Barr is entitled to a declaration that claims of the '398 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112.

Second Counterclaim

Declaration of Invalidity of the '325 Patent

35. Barr hereby repeats and reiterates the allegations of Paragraphs 1 through 29 as if fully set forth herein.

36. This counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and seeks a declaration that claims of the '325 patent is invalid.

37. Plaintiff/Counterclaim Defendant Elan alleges that the '325 patent is infringed, valid, and enforceable, and Barr denies those allegations.

38. A present, genuine, and justiciable controversy exists between Barr and Plaintiff/Counterclaim Defendant Elan regarding the validity of the '325 patent.

39. Barr is entitled to a declaration that claims of the '325 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112.

Third Counterclaim

Declaration of Non-Infringement of the '398 Patent

40. Barr hereby repeats and reiterates the allegations of Paragraphs 1 through 29 as if fully set forth herein.

41. This counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and seeks a declaration that claims of the '398 patent will not be infringed by the manufacture, use, offer for sale, or sale of Barr's ANDA products.

42. A present, genuine justiciable controversy between Barr and Elan regarding whether the manufacture, use, offer for sale, or sale of Barr's ANDA products would infringe claims of the '398 patent.

43. The manufacture, use, offer for sale, or sale of Barr's ANDA products do not and will not infringe any valid claims of the '398 patent.

44. Barr is entitled to a declaration that the manufacture, use, offer for sale, or sale of its ANDA products has not, do not and will not infringe one or more claims of the '398 patent.

Fourth Counterclaim

Declaration of Non-Infringement of the '325 Patent

45. Barr hereby repeats and reiterates the allegations of Paragraphs 1 through 29 as if fully set forth herein.

46. This counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and seeks a declaration that claims of the '325 patent will not be infringed by the manufacture, use, offer for sale, or sale of Barr's ANDA products.

47. A present, genuine justiciable controversy between Barr and Elan regarding whether the manufacture, use, offer for sale, or sale of Barr's ANDA products would infringe claims of the '325 patent.

48. The manufacture, use, offer for sale, or sale of Barr's ANDA products has not, do not and will not infringe any valid claims of the '325 patent.

49. Barr is entitled to a declaration that the manufacture, use, offer for sale, or sale of its ANDA products has not, do not and will not infringe one or more claims of the '325 patent.

PRAYER FOR RELIEF

WHEREFORE, Defendant/Counterclaim Plaintiff Barr Laboratories, Inc. prays that the Court enter judgment against Plaintiffs/Counterclaim Defendants Elan Corporation, PLC and Elan Pharma International LTD., and in favor of Defendant/Counterclaim Plaintiff Barr Laboratories, Inc. as follows:

A. Dismiss the Complaint with prejudice and deny each request for relief made by Elan;

B. For a declaration that Barr Laboratories, Inc.'s ANDA products do not and will not infringe any valid claim of U.S. Patent No. 6,228,398;

C. For a declaration that the claims of U.S. Patent No. 6,228,398 are invalid;

D. For a declaration that Barr Laboratories, Inc.'s ANDA products do not and will not infringe any valid claim of U.S. Patent No. 6,730,325;

E. For a declaration that the claims of U.S. Patent No. 6,730,325 are invalid;

F. For an award of attorneys' fees pursuant to 35 U.S.C. § 285, other statues or rules, or the general power of the Court;

G. For an award of costs;

H. Preliminary and permanently enjoin Elan, their officers, agents, servants, employees, attorneys, and any person who acts in concert or participation with Plaintiffs, from utilizing the '398 and the '325 patents to block, hamper, hinder or obstruct FDA approval of Barr's ANDA products;

I. Permanently enjoin Elan, their officers, agents, servants, employees, attorneys, and any person who acts in concert or participation with Plaintiffs, from asserting or otherwise seeking to enforce the '398 and the '325 patents against Barr or anyone in privity with Barr; and

J. For such other relief as the Court determines to be just and proper.

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